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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,611	10/20/2005	William J. Pavan	015280-148100US	2224

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EXAMINER
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SWOPE, SHERIDAN

ART UNIT	PAPER NUMBER
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1652

MAIL DATE	DELIVERY MODE
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10/04/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

Application No.

10/501,611

Applicant(s)

PAVAN ET AL.

Examiner

Sheridan L. Swope

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 July 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-48 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

Claims 1-48 are pending.

#### *Election/Restrictions*

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-5, drawn to a polynucleotide encoding a rab38 protein.

Group II, Claim 6, drawn to a rab38 protein.

Group III, Claims 7-17, drawn to a method for detecting mutations in a polynucleotide encoding a rab38 protein.

Group IV, Claims 18-23, drawn to a method for screening for agents that modulate a rab38 protein.

Group V, Claims 24-30 and 35-41, drawn to a kit comprising a plurality of melanocytes having a rab38 protein and instructions.

Group VI, Claims 31-34, drawn to a kit comprising primers.

Group VII, Claims 42-45, drawn to a modulator of a rab38 protein.

Group VIII, Claims 46-48, drawn to a method for modulating pigmentation using a modulator of a rab38 protein.

For each of Inventions I-VIII above, restriction to one of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I- VIII and one of Inventions (A)-(T).

If Invention I is elected, elect one of:

- (A) SEQ ID NO: 9
- (B) SEQ ID NO: 10
- (C) SEQ ID NO: 11

Art Unit: 1652

(D) SEQ ID NO: 12

If Invention IV is elected, elect one of:

- (E) GTPase activity (including GTP binding and/or GDP release)
- (F) TYRP1 trafficking to melanosomes
- (G) RAB38 trafficking to melanosomes

If Invention V is elected, elect one of:

- (H) Instructions for analyzing GTPase activity (including GTP binding and/or GDP release)
- (I) Instructions for analyzing TYRP1 trafficking to melanosomes
- (J) Instructions for analyzing RAB38 trafficking to melanosomes

If Invention VI is elected, elect two or more of:

- (K) SEQ ID NO: 17
- (L) SEQ ID NO: 18
- (M) SEQ ID NO: 19
- (N) SEQ ID NO: 20
- (O) SEQ ID NO: 21
- (P) SEQ ID NO: 22

If Invention VII is elected, elect one of:

- (Q) An enhancer
- (R) An inhibitor

If Invention VIII is elected, elect one of:

- (S) An enhancer
- (T) An inhibitor

The inventions listed as Groups I- VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical feature for the following reasons: The technical feature linking Groups I- VIII appears to be that they all relate to rab38 proteins. However, rab38 proteins were known in the art. For example, human rab38 protein is taught by Jager et al, 2000 (Fig 3). Jager et al further teach that rab38 is expressed in most melanoma cells, but not in nonmelanocytic malignancies (Abstract). Thus, the skilled artisan would be motivated to screen for agents that alter rab38 expression and/or activity, which anticipates Claim 18. Therefore Groups I-VIII share no special technical

Art Unit: 1652

feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Furthermore, the products of Groups I, II, and V-VII do not share a special common structural and functional feature while, the methods of Groups III, IV, and VIII do not use the same reagents or produce the same results. In addition, the methods of Groups III, IV, and VIII do not comprise all of the methods for making or using the products of Groups I, II, and V-VII.

Accordingly, Groups I-VIII are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Searching more than one of Groups I-VIII would represent a burden on the Office for the following reasons. Because the products of Groups I, II, and V-VII do not share a special structural and functional feature, a search for any one said product would not encompass a search for any other said products. Thus, a search for more than one of the products of Groups I, II, and V-VII would be a burden on the Office. A search for any one of the methods of Groups III, IV, and VIII would not encompass a search for any other said methods because the methods do not share a special technical feature of steps and products used, or results produced. Thus, the search for more than one of Groups III, IV, and VIII would be a burden on the Office. A search of any one of the products of Groups I, II, and V-VII would not encompass a search of any of the methods of Groups III, IV, and VIII, or vice versa, because said methods are not the only methods of making or using said products. Thus, a search of any one of the products of Groups I, II, and V-VII with any of the methods of Groups III, IV, and VIII would be a burden on the Office.

The searches for any one invention are not required for and are not coextensive with the searches for any other invention, thereby creating an undue burden of search and examination.

Art Unit: 1652

The results from a search of each of these inventions have different considerations with respect to the prior art. Burden lies not only in the search of U.S. patents, but also in the search for literature and foreign patents and in examination of the claim language and specification for compliance with the statutes concerning new matter, distinctness, written description and enablement.

These inventions are distinct for the reasons given above and have acquired a separate status in the art due to their recognized divergent subject matter, as shown by their different classification. Furthermore, as explained above, searching more than one invention would be a burden on the Office. Therefore, restriction for examination purposes, as indicated, is proper. If Applicants should traverse the restriction based on an argument that inventions are not distinct, they should provide evidence as to why the restricted inventions are obvious over their elected invention

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102,

Art Unit: 1652

103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained.

Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Art Unit: 1652


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943.

The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Swope, Ph.D.  
Art Unit 1652



SHERIDAN SWOPE, PH.D.  
PRIMARY EXAMINER